UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.* JULIE LONG, *Relator,* v. JANSSEN BIOTECH, INC., *Defendant.*	Civil Action No. 16-CV-12182-FDS

DEFENDANT'S PRELIMINARY MEMORANDUM REGARDING TRIAL

At the August 26, 2025 status conference, the Court directed the parties to submit briefs regarding their preliminary views as to the proper scope of trial and how to move the case forward. Defendant Janssen Biotech, Inc. ("Janssen") hereby responds to Plaintiff-Relator Julie Long's memorandum filed on September 26, 2025 (Dkt. No. 484).

Janssen agrees with Relator that it is not in the best interests of the parties or the Court to hold two separate jury trials in this matter. Relator's memorandum confirms that, as she has said consistently for years, to the extent her claims survive the Phase One motion for summary judgment, she will need additional fact and expert discovery before a nationwide trial can proceed. *Id.* at 9. She is silent, however, as to what that additional discovery will entail. Janssen submits that, for the reasons discussed below, the scope and timing of any such discovery will only become clear once the motion for summary judgment has been decided. As such, Janssen believes the Court should hold a conference 30 days after summary judgment has been decided, at which time an efficient and appropriate schedule for the remainder of the case, including a nationwide trial if appropriate, can be set by the Court.

I. Relator and Janssen Agree That There Should Not Be Multiple Trials.

As an initial matter, Janssen agrees with Relator that the Court should not require the parties to submit this case to two jury trials. There are clear and significant inefficiencies to holding two separate jury trials, which Relator discusses at length. *Id.* at 8-10. Janssen also notes that the scope of a Phase One trial would be very different than the scope of a nationwide trial. For instance, a Phase One trial would be limited to a few practices that were handpicked by Relator for inclusion in her Complaint (she called on up to 50 accounts, but she only picked a small number of them to feature in her pleadings); and it would be limited to the activities of a single Area Business Specialist ("ABS"), working under a single regional manager, in a portion of a single state (Central Pennsylvania). By contrast, a nationwide trial would involve the activities of ABSs across the country who called on thousands of customers.

II. If Any Part of Relator's Case Survives Summary Judgment, the Court's Ruling and Additional Guidance Will Greatly Inform the Issues for Additional Fact and Expert Discovery and Trial.

A. Relator and Janssen Agree That Additional Fact and Expert Discovery Will Be Required Prior to Any Nationwide Trial.

Relator states that, to the extent her claims survive Janssen's Phase One motion for summary judgment, she will need additional fact and expert discovery before a nationwide trial can proceed. Dkt. No. 484 at 9. Relator neither explains what additional fact and expert discovery will be required, nor states how long that discovery might take, so Janssen is not able to respond to a position Relator might take in the future. Relator's brief only suggests in passing that "because Defendant now has a clear understanding of the Court's discovery expectations given the extensive litigation over discovery during Phase One, this supplemental discovery can be completed quickly and efficiently." *Id.* Honestly, however, Janssen has no idea what that means. Even Relator projects that conducting the necessary supplemental discovery after a Phase

One trial in October 2026 would lead to a nationwide trial in "2028 or later." *Id*. This is consistent with Relator's case schedule proposal from April 2024, where she stated that Phase Two discovery would include (1) the post-2016 period, (2) other customers in Relator's former territory that were not included in "the phase one sample group," (3) customers in other territories across the country, and (4) "certain categories of relevant documents and information that the Court has ruled Janssen does not need to provide during this first phase." Dkt. No. 441 at 3-4. Relator insisted that because Phase One discovery has been limited to "a small sample of accounts and covering only a portion of the relevant period," she would suffer "substantial prejudice" if she were not permitted to "obtain full [Phase Two] discovery before proceeding to a trial of her claims." *Id*. at 8.[1]

Although Relator does not identify the additional discovery she will need before proceeding to a nationwide trial, it is beyond question that it will be extensive. As an initial matter, Phase One is not a bellwether in any sense: the accounts at issue were entirely handpicked by Relator, who obviously selected the practices she thought would be most favorable to her positions in this litigation.

In addition, the activities by Relator as an ABS operating in Central Pennsylvania prior to February 2016 would have only limited relevance to the activities undertaken by all of the other ABSs calling on thousands of other customers across the country over a period of many years. For that reason, a nationwide trial would require extensive testimony from numerous ABSs across the country. Indeed, Relator told the Court that her claims are based not on what the pre-

[1] *See also* Dkt. No. 84 at 4 (proposing that if Relator survives Phase One summary judgment, "a ***second phase*** of discovery would commence regarding Defendant's alleged AKS and FCA violations related to the remaining IOI accounts to which Defendant provided Infusion Business Support, which Plaintiff believes is approximately 1,600 to 2,000 additional accounts").

approved Site of Care programs say on their face, but instead on the activities that she alleges occurred in the room when an ABS was calling on a practice.[2] Clearly, obtaining the type of evidence needed to support a nationwide trial would require significant discovery.

Finally, Relator advocates for a nationwide trial through the present, more than doubling the current temporal range of at-issue claims. Whatever she has in mind, this will no doubt take some time. For example, Phase One has included document discovery regarding the relevant policies in place during the Phase One period, the at-issue Site of Care Programs approved for use during the Phase One period, and the role and activity of ABSs during the Phase One period. It has also included depositions to discuss policies, procedures, guidance, training, and activities during the Phase One period. If the court were to permit such a massive extension of the time period, presumably Relator would seek discovery to cover the approximately 9 years (as of today) after the Phase One period about which Relator has no personal knowledge. Relator relentlessly pursued Phase One discovery, which led Janssen to produce documents from 84 custodians and Relator to take 20 depositions of Janssen witnesses. Janssen would also need additional discovery for this post Phase One period, including government discovery, given the unique legal issues that apply to claims premised on post-complaint conduct.

B. Summary Judgment Will Inform How Further Discovery Will Proceed.

Janssen further submits that the scope and timing of any such discovery will only become clear once summary judgment has been decided. In Janssen's view, this case will be disposed of through the upcoming summary judgment process. As the Court has noted, if Relator's case were

[2] *See* Dkt No. 400 at 12 ("Relator does not allege that the slide decks and other visual aids themselves were the Services or presentations that constitute the remuneration/kickbacks . . . ."); Dkt. No. 433 at 2 ("She contends that the interrogatory response does not identify the slideshow presentations themselves as violating the Anti-Kickback Statute and the False Claims Act.").

to survive in some fashion, the scope of those claims might look far different than the broad allegations Relator has been pursuing to date. *See* Dkt. No. 320 at 2 (ruling that phasing discovery "will provide defendants an opportunity to test the allegations of the complaint by summary judgment, which might narrow or eliminate her claims altogether").

Relator spends several pages of her brief rehashing the allegations in her Complaint, based on her apparent belief that they are relevant to how to move the case forward. She claims Janssen had ABSs provide "free consultative services" to IOI customers; the free consultative services were a kickback to induce physicians to prescribe Janssen's products; Janssen provided the free consultative services to "high-volume" practices it "targeted" as susceptible to a kickback; and Janssen did so despite knowing that providing the free consulting services to those customers was illegal. Dkt. No. 484 at 3-4. But fact discovery has closed and the time for broad allegations has passed. While in every prior discussion Janssen has had with the Court (the motion to dismiss and discovery motions) it has had to focus on those allegations, what will actually be relevant to how to move the case forward after summary judgment will be the established facts and the Court's ruling.

And those facts are not consistent with Relator's allegations. At the outset of the case, when the Court directed the parties to proceed with an initial phase of discovery focused on the accounts in Central Pennsylvania that Relator had handpicked for inclusion in her Complaint, the Court noted that "[t]he facts on the ground aren't always what they are as alleged in the complaint." Dec. 14, 2020 Conf. Tr. (Dkt. No. 90) at 10:16-17; *see also id.* at 17-19 ("Sometimes they're better for the plaintiff, sometimes they are worse, but they tend to be different . . . ."). That is true here. As illustrated below, there are significant differences between Relator's

allegations and reality, and Relator's case faces very significant hurdles.[3] In all events, summary judgment will inform the parties and the Court about how to most efficiently streamline the case if any part of it survives.

First, the purpose and implementation of ABS programs. Unlike many pharmaceutical products (*e.g.*, a pill that can be administered with a glass of water), the products at issue in this case required not only a prescription, but also an infusion. This often involved two different healthcare providers at two different locations: one for the prescription (which Janssen referred to as the "Site of Demand") and another for the infusion (which Janssen referred to as the "Site of Care"). The "Site of Care" could be a hospital, an in-office infusion suite ("IOI"), or an infusion center. The ABS team provided education to all sites of care, but Relator limits her allegations to ABS activities in IOIs. According to Relator's allegations, ABSs increased sales by providing free consulting to IOIs as a kickback in exchange for prescriptions of Janssen's products. According to Janssen, the evidence shows that no "free consulting" occurred. The focus of the ABS team was to help improve patient access to appropriately prescribed medications. The ABSs did this by delivering pre-approved "Site of Care" programs designed to provide education on high-level considerations involving various topics. The point of the Site of Care programs was to encourage the practices or hospitals to evaluate ways they could ensure that patients received their infusions in a timely manner, prevent patient attrition and delays in infusions, and improve patient outcomes.

[3] To be clear, Janssen is not attempting to force Relator to respond to the positions Janssen has taken in this brief, nor does Janssen believe that would be productive. The time for that will be in Relator's opposition to Janssen's motion for summary judgment, which is set to be filed in less than six months. Instead, Janssen is highlighting examples of the differences between Relator's allegations and what it believes the case will look like if her claims survive summary judgment.

Second, Relator's allegations of "targeting." A key part of Relator's theory has always been the allegation that Janssen "targeted" specific "high-volume" IOI customers. Dkt. No. 484 at 3. It is true that, like for any team of field representatives, it was not possible for ABSs to literally call on every potential prescriber of Remicade across the country. The evidence shows, however, that the ABS team called on all accounts except those with very low prescription volumes. In other words, unlike a kickback scheme, Janssen was not targeting specific customers it believed were susceptible to a kickback. Instead, ABSs were given a call list of the type used with any other team of field representatives.

In addition, ABSs delivered Site of Care programs not only to IOI accounts, but also to Hospital Out-Patient Departments ("HOPDs"). Relator has admitted that there was no kickback when the Site of Care programs were delivered to HOPDs. Dkt. No. 55 at 78 n.14. But the evidence shows that of all customers, HOPD accounts received the highest volume of Site of Care programs. This is entirely inconsistent with Relator's theory that the Site of Care programs were kickbacks, and entirely consistent with Janssen's position that they were educational programs delivered to all Sites of Care to help ensure that prescriptions that were written could actually be infused to appropriate patients.

Third, Relator's allegations of unlawful intent under the Anti-Kickback Statute and the False Claims Act. Relator alleges that Janssen knew that providing the Site of Care programs to IOI customers was illegal but did it anyway to induce prescriptions. Dkt. No. 484 at 3-4. Janssen will show that there is no evidence that anyone at Janssen believed the Site of Care programs were unlawful.

For purposes of Phase One, Relator was the one delivering the alleged kickbacks, and the Phase One accounts were the ones receiving the alleged kickbacks. Relator's own testimony

confirms that throughout her 13-year tenure as an ABS, she never thought she was providing a kickback or doing anything improper. That is particularly notable because Relator was not just a typical ABS—she also served as a Healthcare Compliance Liaison, acting as an interface between the ABS team and Janssen's Health Care Compliance department. This involved, among other things, providing presentations to other ABSs regarding Janssen's compliance policies—which included a strict prohibition against providing free consulting to customers. Relator not only testified that she never thought she was providing a kickback, but she also testified that she never thought she was providing free consulting. Relator emphasized this point by explaining that she knew individuals from another pharmaceutical company that had gone to jail for doing that.[4]

Nor is there any evidence that any practices ever believed they were receiving a kickback. While Relator alleges that the practices were receiving kickbacks with "significant value" that induced them to prescribe Janssen's products, Dkt. No. 484 at 3, she testified that no practice ever suggested she was providing a kickback or discussed any such thing with her. Instead, the evidence shows that despite receiving the Site of Care programs from Relator, many of the Phase One accounts simultaneously paid third-party consulting firms to provide consulting services to their practices. That is inconsistent with the allegation that Relator was already providing free consulting services to those same practices that obviated the need for them to hire consultants, let alone that they prescribed Remicade in exchange for receiving the Site of Care programming in order to save money on hiring their own advisors.

[4] According to Relator, she did not believe she was doing anything wrong until she left Janssen and began talking with her attorneys. *See* Mar. 17, 2023 Relator's Resp. to Interrog. 9 ("Plaintiff first became aware that the in-office infusion support services that Janssen provided violated the law in or around the second quarter of 2016 after she had retained counsel.").

Fourth, whether claims "resulted from" AKS violations. Relator previously told the Court that, until the First Circuit determined whether the statutory "resulting from" language required proof of but-for causation, it would be "wasteful" to require Relator "to conduct discovery of non-parties, such as recipients of the alleged kickbacks, or engage experts to opine on causation." Dkt. No. 441 at 4. In February 2025, the First Circuit confirmed that the "resulting from" path requires proof of but-for causation, but it left open the possibility of proceeding on a separate false certification path. *See United States v. Regeneron Pharms., Inc.*, 128 F.4th 324, 333 (1st Cir. 2025).

Relator now tells the Court that she is "litigating her FCA claims under both theories of liability." Dkt. No. 484 at 5 n.7. That is a surprise, because in a March 2025 hearing immediately after the *Regeneron* opinion was issued, Relator's counsel told the Court that in light of *Regeneron* she had elected to proceed under the false certification path, and she did not intend to pursue any causation discovery from any of the Phase One accounts. Mar. 14, 2025 Conf. Tr. (Dkt. No. 468) at 6:4-7:6; *see also id.* at 13:15-16 ("As I mentioned, a little bit ago, we intend to pursue this case on the false certification theory."). In any event, with respect to the statutory "resulting from" path, Relator has no evidence to even begin to satisfy the but-for causation standard.

Fifth, Relator's alternative "false certification" theory. Relator alleges that every claim submitted during Phase One was submitted on a CMS Form 1500 that contained an express false certification of compliance with the AKS. Relator has a problem: the evidence shows that this is not true. In fact, there is no evidence that any claim submitted to the government included such a certification. *See* Ex. A (Oct. 6, 2025 Expert Report of Brett E. Barlag). This will be fatal to Relator's false certification theory.

Sixth, Relator's allegations of materiality. This is a case in which the government has continued to pay all claims long after Relator alerted the government to her allegations. The evidence shows that for over a decade Janssen had been submitting many of the Site of Care programs to the FDA for review pursuant to regulatory requirements applicable to certain customer-facing promotional material. The evidence also shows that when Relator filed her Complaint under seal, the government conducted an extensive investigation which included a detailed document subpoena requesting, among other things, all of the Site of Care programs; multiple interviews of Relator herself; and an all-day investigative hearing during which it questioned a different ABS. Despite that, the government elected not to intervene. Thereafter, even though the government has been aware that Janssen has continued to provide the Site of Care programs, it has continued to pay all claims submitted by providers who received the Site of Care programs. That is powerful evidence of lack of materiality, which the Supreme Court said courts must consider when deciding a dispositive motion. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192-96 (2016).

III. Summary of Proposed Approach.

For the above reasons, to the extent Relator's claims were to survive summary judgment, Janssen respectfully requests that the Court proceed by setting a hearing to take place 30 days after summary judgment has been decided, and instructing the parties to both confer and submit detailed proposals in advance of that hearing addressing the length and scope of remaining discovery and a proposed pre-trial schedule, including proposals for fact discovery, expert discovery, and any other necessary proceedings in advance of a nationwide trial.

That will enable the Court to set an efficient and appropriate schedule for the remainder of the case. There are many reasons for this. First, Relator will be able to assess what claims she wants to continue to pursue. Second, Relator will have information to assess the amount and type

of discovery she will need to support nationwide claims, and Janssen will have information to assess additional discovery it needs to defend itself, including discovery from the government. Third, the Court will be better positioned to assess Relator's request to extend the time period to the present.[5]

Dated: October 17, 2025

Respectfully Submitted,

/s/ Jason C. Raofield

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[5] Janssen does not know why Relator filed a brief vaguely suggesting supplemental discovery could be completed efficiently, without saying anything about either what that discovery would involve or how long it would take. But if Relator intends to ask that a nationwide trial be scheduled to take place quickly after a decision on the Phase One summary judgment motion, that issue should be briefed immediately. There are many reasons for this, but Janssen will not get into that now as Relator has not taken that position. This is an important matter that could cause Janssen substantial prejudice, and it should not be decided during a status conference without briefing.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

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